103D CONGRESS 1ST SESSION

S. 516

To amend title XVIII of the Social Security Act to improve procedures under part B of the medicare program relating to durable medical equipment, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 5 (legislative day, MARCH 3), 1993

Mr. PRYOR (for himself, Mr. Sasser, Mr. Cohen, Mr. Grassley, Mr. Conrad, Mr. Durenberger, Mr. Leahy, and Mr. McCain) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

- To amend title XVIII of the Social Security Act to improve procedures under part B of the medicare program relating to durable medical equipment, and for other purposes.
 - 1 Be it enacted by the Senate and House of Representa-
 - 2 tives of the United States of America in Congress assembled,
 - 3 SECTION 1. REFERENCES TO SOCIAL SECURITY ACT.
 - 4 Except as otherwise specifically provided, whenever in
 - 5 this Act an amendment is expressed in terms of an amend-
 - 6 ment to or repeal of a section or other provision, the ref-

1	erence shall be considered to be made to that section or
2	other provision of the Social Security Act.
3	SEC. 2. DURABLE MEDICAL EQUIPMENT.
4	(a) Definition of Medical Equipment and Sup-
5	PLIES.—
6	(1) In General.—Section 1861 (42 U.S.C.
7	1395x) is amended by adding at the end the follow-
8	ing new subsection:
9	"MEDICAL EQUIPMENT AND SUPPLIES
10	"(00) The term 'medical equipment and supplies"
11	means—
12	"(1) durable medical equipment (as defined in
13	section 1861(n));
14	"(2) prosthetic devices (as described in section
15	1861(s)(8));
16	"(3) orthotics and prosthetics (as described in
17	section 1861(s)(9));
18	"(4) home dialysis supplies and equipment (as
19	described in section 1861(s)(2)(F));
20	"(5) surgical dressings and other devices (as
21	described in section 1861(s)(5));
22	"(6) immunosuppressive drugs (as described in
23	section $1861(s)(2)(J)$; and
24	"(7) such other items as the Secretary may de-
25	termine.".

1	(2) Effective date.—The amendment made
2	by paragraph (1) shall apply to items furnished on
3	or after January 1, 1994.
4	(b) Development and Application of National
5	STANDARDS FOR SUPPLIERS OF MEDICAL EQUIPMENT
6	AND SUPPLIES.—Section 1834 (42 U.S.C. 1395m) is
7	amended by adding at the end the following new sub-
8	section:
9	"(i) REQUIREMENTS FOR ISSUANCE AND RENEWAL
10	OF SUPPLIER NUMBERS FOR SUPPLIERS OF MEDICAL
11	EQUIPMENT AND SUPPLIES.—
12	"(1) Payment.—No payment may be made
13	under this part after July 1, 1994, for items fur-
14	nished by a supplier of medical equipment and sup-
15	plies (as defined in section 1861(00)) unless such
16	supplier meets the national standards specified by
17	the Secretary and possesses a valid supplier number.
18	"(2) Revised Standards.—
19	"(A) IN GENERAL.—The Secretary shall,
20	by no later than January 1, 1996, in consulta-
21	tion with representatives of suppliers of medical
22	equipment and supplies, carriers, and consum-
23	ers, revise the national standards for suppliers
24	of medical equipment and supplies to include
25	the requirements listed in subparagraph (B).

1	"(B) STANDARDS DESCRIBED.—The re-
2	quirements listed in this subparagraph are that
3	suppliers of medical equipment and supplies
4	shall—
5	"(i) comply with all applicable State
6	and Federal licensure and regulatory re-
7	quirements;
8	"(ii) maintain a physical facility on an
9	appropriate site;
10	"(iii) have proof of appropriate liabil-
11	ity insurance; and
12	"(iv) meet such other requirements as
13	the Secretary may specify.
14	"(C) Applicability of revised stand-
15	ARDS.—Beginning after December 31, 1995,
16	each supplier of medical equipment and supplies
17	applying for a supplier number or renewing
18	such supplier's supplier number shall meet the
19	revised standards described in this paragraph.".
20	(c) Certificates of Medical Necessity.—
21	(1) IN GENERAL.—Section 1834 (42 U.S.C.
22	1395m), as amended by subsection (b), is
23	amended—
24	(A) in subsection (a), by striking para-
25	graph (16), and

1	(B) by adding at the end the following new
2	subsection:
3	"(j) Certificates of Medical Necessity.—
4	"(1) Standardized certificates.—Not later
5	than July 1, 1994, the Secretary shall, in consulta-
6	tion with carriers under this part, develop one or
7	more standardized certificates of medical necessity
8	(as defined in paragraph (3)) for medical equipment
9	and supplies (as defined in section 1861(oo) other
10	than paragraphs (4), (6), and (7)). If a certificate
11	of medical necessity is required by the Secretary,
12	such standardized certificates shall—
13	"(A) be completed by each physician who
14	prescribes such medical equipment and supplies
15	for any beneficiary under this part, and
16	"(B) be transmitted to the supplier and
17	then to the carrier processing the claim for pay-
18	ment for such medical equipment and supplies
19	under this part.
20	"(2) Prohibition against distribution by
21	SUPPLIERS OF CERTIFICATES OF MEDICAL NECES-
22	SITY.—
23	"(A) IN GENERAL.—Except as provided in
24	subparagraph (B), a supplier of medical equip-
25	ment and supplies described in paragraph (1)

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may not distribute to physicians or to individuals entitled to benefits under this part for commercial purposes any completed or partially completed certificates of medical necessity.

"(B) EXCEPTION FOR CERTAIN BILLING INFORMATION.—Subparagraph (A) shall not apply with respect to a certificate of medical necessity to the extent that such certificate contains only information completed by the supplier of medical equipment and supplies identifying such supplier and the beneficiary to whom such medical equipment and supplies are furnished, a description of such medical equipment and supplies, any product code identifying such medical equipment and supplies, and any other administrative information identified by the Secretary. In the event a supplier provides a certificate of medical necessity containing information permitted under this subparagraph, such certificate shall also contain the supplier's charge and the fee schedule amount for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

"(C) PENALTY.—Any supplier of medical 1 equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of subparagraph (A) is subject to a civil money penalty in an amount not to exceed \$1,000 for each such certificate of medical necessity so distributed. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1128A(a).

- "(3) DEFINITION.—For purposes of this subsection, the term 'certificate of medical necessity' means a form or other document containing information required by the Secretary to be submitted to show that a covered item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.".
- (2) Effective date.—The amendments made by paragraph (1) shall apply with respect to certificates of medical necessity on or after January 1, 1994.

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- 1 (d) COVERAGE AND REVIEW CRITERIA FOR CERTAIN
- 2 Medical Equipment and Supplies.—Section 1834 (42)
- 3 U.S.C. 1395m), as amended by subsection (c), is amended
- 4 by adding at the end the following new subsection:
- 5 "(k) COVERAGE AND REVIEW CRITERIA.—

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- "(1) DEVELOPMENT AND ESTABLISHMENT.— Not later than July 1, 1994, the Secretary, in consultation with representatives of suppliers of medical equipment and supplies (as defined in section 1861(00) other than paragraphs (4), (6), and (7)), individuals enrolled under this part, and appropriate medical specialty societies, shall develop and establish uniform national coverage and utilization review criteria for 200 items of medical equipment and supplies (as so defined) selected in accordance with the standards described in paragraph (2). The Secretary shall publish the criteria as part of the instructions provided to fiscal intermediaries and carriers under this part and no further publication, including publication in the Federal Register, shall be required.
 - "(2) STANDARDS FOR SELECTING ITEMS SUB-JECT TO CRITERIA.—The Secretary may select an item for coverage under the criteria developed and established under paragraph (1) if the Secretary finds that—

1	"(A)	the	item	is	frequently	purchased	or
2	rented by	bene	eficiar	ies;			

- "(B) the item is frequently subject to a determination that such item is not medically necessary; or
- "(C) the coverage or utilization criteria applied to the item (as of the date of the enactment of this subsection) is not consistent among carriers.
- "(3) Annual review and expansion of items subject to criteria.—The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether items not included among the items selected under paragraph (1) should be made subject to uniform national coverage and utilization review criteria, and, if appropriate, shall develop and apply such criteria to such additional items.
- "(4) Report on Effect of Uniform Criteria on Utilization of Items.—Not later than January 1, 1995, the Secretary shall submit a report to the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate analyzing the impact of the uniform cri-

1	teria established under paragraph (1) on the utiliza-
2	tion of items of medical equipment and supplies by
3	individuals enrolled under this part.".
4	(e) Prohibition Against Multiple Supplier
5	Numbers.—
6	(1) IN GENERAL.—Section 1834 (42 U.S.C.
7	1395m), as amended by subsection (d), is amended
8	by adding at the end the following new subsection:
9	"(1) PROHIBITION AGAINST MULTIPLE SUPPLIER
10	Numbers for Suppliers of Medical Equipment and
11	Supplies.—The Secretary may not issue more than one
12	supplier number to any supplier of medical equipment and
13	supplies (as defined in section 1861(oo)) unless the issu-
14	ance of more than one number is appropriate to identify
15	subsidiary or regional entities under the supplier's owner-
16	ship or control.".
17	(2) Effective date.—The amendment made
18	by paragraph (1) shall apply to items furnished on
19	or after July 1, 1994.
20	(f) Definition of Inducements as Kickbacks
21	Clarified.—
22	(1) IN GENERAL.—Section 1128B(b)(3)(B) (42
23	U.S.C. 1320a-7b(b)(3)(B)) is amended by inserting
24	before the semicolon "(except that in the case of a
25	contract supply arrangement between a skilled nurs-

1	ing facility and a supplier of medical supplies and
2	equipment (as defined in section 1861(00) other
3	than paragraphs (4), (6), and (7)), such employment
4	shall not be considered bona fide to the extent that
5	it includes tasks of a clerical and cataloging nature
6	in transmitting to suppliers assignment rights of in-
7	dividuals eligible for benefits under part B of title
8	XVIII, or performance of warehousing or stock in-
9	ventory functions)".
10	(2) Effective date.—The amendment made
11	by paragraph (1) shall apply with respect to services
12	furnished on or after January 1, 1994.
13	(g) Limitation on Beneficiary Liability.—
14	(1) IN GENERAL.—Section 1879 (42 U.S.C.
15	1395pp) is amended by adding at the end the follow-
16	ing new subsection:
17	"(h) If a supplier of medical equipment and supplies
18	(as defined in section 1861(oo))—
19	"(1) furnishes an item or service to a bene-
20	ficiary for which no payment may be made by reason
21	of section 1834(i);
22	"(2) furnishes an item or service to a bene-
23	ficiary for which payment is denied in advance under
24	section 1834(a)(15);

1	"(3) is excluded from participation under this
2	title; or
3	"(4) furnishes an item or service to a bene-
4	ficiary for which payment is denied under section
5	1862(a)(1);
6	any expenses incurred for items and services furnished to
7	an individual by such a supplier on an unassigned basis
8	shall be the responsibility of such supplier. The individual
9	shall have no financial responsibility for such expenses and
10	the supplier shall refund on a timely basis to the individual
11	(and shall be liable to the individual for) any amounts col-
12	lected from the individual for such items or services, un-
13	less the supplier informs the individual in advance that
14	payment under this part will not be made for the item
15	or services and the individual agrees to pay for the item
16	or service.".
17	(2) Effective date.—The amendment made
18	by paragraph (1) shall apply to items or services
19	furnished on or after July 1, 1994.
20	(h) Treatment of Nebulizers and Aspirators
21	AS MISCELLANEOUS ITEMS OF DURABLE MEDICAL
22	EQUIPMENT.—
23	(1) IN GENERAL.—Section 1834(a)(3)(A) (42
24	U.S.C. 1395m(a)(3)(A)) is amended by striking
25	"ventilators, aspirators, IPPB machines, and

1	neounzers and inserting ventuators and IPPB ma-
2	chines".
3	(2) PAYMENT FOR SUPPLIES RELATING TO
4	NEBULIZERS AND ASPIRATORS.—Section
5	1834(a)(7)(A) (42 U.S.C. $1395m(a)(7)(A)$) is
6	amended by striking "and" at the end of clause (v),
7	by striking the period at the end of clause (vi) and
8	inserting "; and", and by inserting after clause (vi)
9	the following new clause:
10	"(vii) In the case of supplies to be
11	used in conjunction with a nebulizer or as-
12	pirator for which payment is made under
13	this paragraph, payment shall be in ac-
14	cordance with paragraph (2) of this sub-
15	section.".
16	(3) Effective date.—The amendments made
17	by this subsection shall apply to items furnished on
18	or after January 1, 1994.
9	(i) PAYMENT FOR OSTOMY SUPPLIES, TRACHE-
20	OSTOMY SUPPLIES, UROLOGICALS, SURGICAL DRESSINGS,
21	AND OTHER MEDICAL SUPPLIES.—
22	(1) In GENERAL.—Section 1834(h)(1) (42
23	U.S.C. 1395m(h)(1)) is amended by adding at the
24	end the following new subparagraph:

1	"(E) EXCEPTION FOR CERTAIN ITEMS.—
2	Payment for ostomy supplies, tracheostomy
3	supplies, urologicals, surgical dressings, and
4	other medical supplies shall be made in accord-
5	ance with subparagraphs (B) and (C) of section
6	1834(a)(2) (except that in the case of surgical
7	dressings, the national limited payment amount
8	shall be computed based on local payment
9	amounts using average reasonable charges for
10	the six-month period ending June 30, 1993, in-
11	creased by the covered item update for 1994).".
12	(2) Effective dates.—
13	(A) In general.—Except as provided in
14	subparagraph (B), the amendment made by
15	paragraph (1) shall apply with respect to items
16	furnished on or after January 1, 1994.
17	(B) SURGICAL DRESSINGS AND OTHER
18	MEDICAL SUPPLIES.—The amendment made by
19	paragraph (1) with respect to surgical dressings
20	and other medical supplies shall apply to items
21	supplied on or after July 1, 1994.
22	(j) Freeze in Reasonable Charges for Paren-
23	TERAL AND ENTERAL NUTRIENTS, SUPPLIES, AND
24	EQUIPMENT DURING 1994.—In determining the amount
25	of payment under part B of title XVIII of the Social Secu-

- 1 rity Act during 1994, the charges determined to be rea-
- 2 sonable with respect to parenteral and enteral nutrients,
- 3 supplies, and equipment may not exceed the charges deter-
- 4 mined to be reasonable with respect to such nutrients,
- 5 supplies, and equipment during 1993.

(k) STUDIES.—

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- (1) SUPPLIES AND SERVICES IN NURSING FA-CILITIES.—The Comptroller General of the United States shall conduct a study and report to the Congress no later than January 1, 1995, on the types, volume, and utilization of services and supplies furnished under contract or under arrangement with suppliers to individuals eligible for benefits under title XVIII of the Social Security Act residing in skilled nursing facilities and nursing facilities.
- (2) DESCRIPTIONS RELATING TO CERTAIN CODES.—The Comptroller General of the United States shall conduct a study beginning no earlier than July 1, 1994, and report to the Congress no later than January 1, 1995, on—
- (A) whether changes made by the Department of Health and Human Services to the descriptions relating to the codes for medical equipment and supplies (as defined in section



1	1861(00) of the Social Security Act other than
2	paragraphs (4), (6), and (7))—
3	(i) accurately reflect the items being
4	furnished under such codes, and
5	(ii) are sufficiently explicit to distin-
6	guish between items of varying quality and
7	price, and
8	(B) recommendations for additional
9	changes that would improve the descriptions re-
10	lating to the codes for such items.